

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of: SETTE <i>et al.</i> Patent No.: 7,507,803 B2 Issued: March 24, 2009 For: Optimized Multi-Epitope Constructs and Uses Thereof	Confirmation No.: 5542 Art Unit: 1648 Examiner: Nicole Erin Kinsey White Atty. Docket: 2473.0200003/EKS/PAC
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**Request for Reconsideration of Patent Term Adjustment
Determination Under 37 C.F.R. § 1.705(d)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Mail Stop Patent Ext.

Sir:

Pursuant to 37 C.F.R. § 1.705(d), Patentees submit a Request for Reconsideration of Patent Term Adjustment in the captioned patent within two months of the date the patent issued. The issues raised in this Request pertain to the issue date of the captioned patent and therefore are timely because they could not have been raised in an application for patent term adjustment under 37 C.F.R. § 1.705(b). Pursuant to 37 C.F.R. §§ 1.705(b) and 1.705(d), Patentees provide a concise statement of facts involved and a payment of the fee set forth in 37 C.F.R. § 1.18(e).

Statement of the Facts:

Patentees hereby request that the patent term adjustment for the captioned patent be corrected to allow an additional 659 days to the current patent term adjustment of 744 days, such that the total patent term adjustment is 1403 days. 37 C.F.R. § 1.705(b)(2)(i). Pursuant to 37 C.F.R. § 1.705(b)(2)(ii), Patentees provide the following summary of relevant dates for which an adjustment is sought under 37 C.F.R. §§ 1.703(a)-(e) and for which an adjustment under 37 C.F.R. § 1.703(f) is entitled.

The period of adjustment of patent term under 37 C.F.R. §§ 1.702(a) and 1.703(a) is 832 days.

According to 37 C.F.R. § 1.703(a), the period of adjustment of patent term due to examination delay under 37 C.F.R. § 1.702(a) is the sum of the periods specified in 37 C.F.R. §§ 1.703(a)(1)-(6). One such period is the period beginning on the day after the date that is 14 months after the date on which the application was filed and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first. 37 C.F.R. § 1.703(a)(1).

The application from which the captioned patent issued, Appl. No. 10/677,754, was filed on October 3, 2003. The United States Patent and Trademark Office (USPTO) mailed a Restriction Requirement on March 15, 2007, creating a period of adjustment under 37 C.F.R. § 1.703(a) of 832 days, calculated as the period beginning on the day after February 3, 2005 (*i.e.*, the date that is 14 months after the actual filing date of the application) and ending on March 15, 2007 (*i.e.*, the earlier of the date of mailing of an action under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151).

The period of adjustment of patent term under 37 C.F.R. §§ 1.702(b) and 1.703(b) is 730 days.

According to 37 C.F.R. § 1.703(b), the period of adjustment of patent term due to examination delay under 37 C.F.R. § 1.702(b) is the number of days in the period beginning on the day after the date that is three years after the filing date of the application and ending on the date the patent issued. The period of adjustment does not include periods of overlap with the adjustment calculated under 37 C.F.R. § 1.702(a). The period of adjustment under 37 C.F.R. § 1.702(b) also does not include the sum of: (1) certain periods related to the filing of a request for continued examination (*see* 37 C.F.R. § 1.703(b)(1)); (2) certain periods related to the declaration or redeclaration of an interference, or the suspension of prosecution by the USPTO due to interference proceedings (*see* 37 C.F.R. § 1.703(b)(2)); (3) certain periods related to the maintenance of an application in a sealed condition or involving

the filing of a secrecy order (*see* 37 C.F.R. § 1.703(b)(3)); and (4) certain periods related to the filing of a notice of appeal (*see* 37 C.F.R. § 1.703(b)(4)).

The USPTO issued the captioned patent on March 24, 2009. None of the conditions under 37 C.F.R. §§ 1.703(b)(1)-(4) are applicable to the captioned patent. Therefore, the issuance of the captioned patent created a period of adjustment under 37 C.F.R. § 1.703(b) of 730 days, calculated as the period beginning on the day after October 3, 2006 (*i.e.*, the date three years from the actual filing date of the application) and ending on February 24, 2009 (*i.e.*, the date the patent issued) minus the overlap period calculated from 37 C.F.R. § 1.703(a) (*i.e.*, the period between October 3, 2006, three years from the actual filing date of the application, and March 15, 2007, the mailing date of the Restriction Requirement).

The period of adjustment of patent term is reduced under 37 C.F.R. § 1.704.

According to 37 C.F.R. § 1.704, the period of adjustment of patent term under 37 C.F.R. §§ 1.702(a)-(e) and 1.703(a)-(e) is reduced by certain periods of time specified in 37 C.F.R. §§ 1.704(a)-(e). Patentees believe that the information recorded in the Patent Application Information Retrieval (PAIR) system correctly indicates that the Applicants' delay under 37 C.F.R. § 1.704 is 159 days.

The USPTO's calculation of adjustment of patent term.

According to 37 C.F.R. § 1.703(f),

[t]o the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed. The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the period calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704.

See also 35 U.S.C. § 154(b)(2)(A). According to guidance from the USPTO, if an application is entitled to an adjustment under the three-year pendency period of 35 U.S.C. § 154(b)(1)(B) (implemented by the USPTO in 37 C.F.R. §§ 1.702(b) and 1.703(b)), the entire period during which the application was pending before the USPTO (excluding the periods specified in 35 U.S.C. § 154(b)(1)(B)(i)-(iii)) is the relevant period for determining whether periods of delay overlap with 35 U.S.C. § 154(b)(1)(A) (implemented by the USPTO in 37 C.F.R. §§ 1.702(a) and 1.703(a)). *See, e.g.*, 69 Fed. Reg. 34283 (June 21, 2004). As such, the USPTO interprets 37 C.F.R. § 1.703(f) as not permitting patent term adjustment under both 37 C.F.R. § 1.703(a) and 37 C.F.R. § 1.703(b), and therefore grants the larger of the period of delay under 37 C.F.R. § 1.703(a) or the period of delay under 37 C.F.R. § 1.703(b).

According to the information currently recorded in the PAIR system, the patent term adjustment of the captioned patent is 744 days, the larger of the periods of delay under 37 C.F.R. § 1.703(a) and 37 C.F.R. § 1.703(b).

The proper calculation of adjustment of patent term under Wyeth v. Dudas results in a total patent term adjustment of 1403 days.

On September 30, 2008, the U.S. District Court for the District of Columbia decided *Wyeth v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008) ("*Wyeth*") (attached as Exhibit A). In view of *Wyeth*, Patentees submit that the captioned patent is entitled an additional 659 days of patent term adjustment, such that the total patent term adjustment is 1403 days.

In *Wyeth*, the District Court disagreed with the USPTO's interpretation that the entire period during which an application is pending before the USPTO (excluding the periods of 35 U.S.C. § 154(b)(1)(B)(i)-(iii)) is the relevant period for determining whether periods of delay under 35 U.S.C. § 154(b)(1)(B) (37 C.F.R. §§ 1.702(b) and 1.703(b)) overlap with periods of delay under 35 U.S.C. § 154(b)(1)(A) (37 C.F.R. §§ 1.702(a) and 1.703(a)). Specifically, the District Court disagreed with the USPTO's interpretation because it considers an application as delayed under 35 U.S.C. § 154(b)(1)(B) during the period before it has been delayed under the three-year

pendency provision. *See, e.g., Wyeth* at pages 8-9. In addition, the District Court found the language in 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) regarding the overlap of the periods was not ambiguous and indicated that delays under 35 U.S.C. § 154(b)(1)(B) ("B delays" in *Wyeth*) begin "when the PTO has failed to issue a patent within three years, not before." *Wyeth* at page 9.

In view of *Wyeth*, it is clear that delays under 35 U.S.C. § 154(b)(1)(B) (and therefore under 37 C.F.R. §§ 1.702(b) and 1.703(b)) do not begin until the USPTO has failed to issue a patent within three years, subject to the exclusions of 35 U.S.C. § 154(b)(1)(B)(i)-(iii). In the captioned patent, the period of adjustment under 37 C.F.R. § 1.703(a), ending on March 15, 2007 overlaps with the period of adjustment under 37 C.F.R. § 1.703(b) beginning on the day after October 3, 2006 by 172 days. Accordingly, Patentees are entitled to the period of adjustment under both 37 C.F.R. § 1.703(a) and 37 C.F.R. § 1.703(b), minus the period of overlap between the two, rather than only the period under 37 C.F.R. § 1.703(a) as currently calculated. As such, Patentees are entitled to an additional 659 days of patent term adjustment for the period of delay under 37 C.F.R. §§ 1.703(b) and 1.704, such that the total patent term adjustment is 1403 days.

Pursuant to 37 C.F.R. § 1.705(b)(2)(iii), the captioned patent is not subject to a terminal disclaimer.

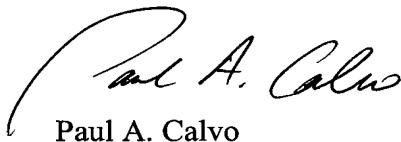
Pursuant to 37 C.F.R. § 1.705(b)(2)(iv), Patentees are not aware of any circumstances during the prosecution of the application constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704.

Pursuant to 37 C.F.R. § 1.705(b)(1), the fee set forth in 37 C.F.R. § 1.18(e) is provided in our accompanying Online Credit Card Payment Authorization. It is not believed that additional fees are required beyond those that may otherwise be provided in documents accompanying this paper. However, if additional fees are required, the USPTO is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

If it is believed, for any reason, that personal communication will expedite consideration of this Request, please do not hesitate to telephone the undersigned at the number provided. Prompt and favorable consideration of this Request is respectfully requested.

Respectfully submitted,

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EXHIBIT A

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WYETH, et al., :
: Plaintiff, :
: v. : Civil Action No. 07-1492 (JR)
: JON W. DUDAS, Under Secretary of :
Commerce for Intellectual :
Property and Director of U.S. :
Patent and Trademark Office, :
: Defendant. :

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds

specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the “[g]uarantee of prompt Patent and Trademark Office response.” It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called “A delays” or “A periods.” The second provision is the “[g]uarantee of no more than 3-year application pendency.” Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.¹ See 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the “B delay” or the “B period”. (“C delays,” delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

¹ Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b)(1)(b)(i)-(iii), as are periods attributable to the applicant’s own delay. See 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B) (i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is

1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under Chevron v. NRDC, 467 U.S. 837 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in Gonzales v. Oregon, 546 U.S. 243 (2006), and United States v. Mead Corp., 533 U.S. 218 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority.

See Gonzales, 546 U.S. at 255-56, citing Mead, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in Merck, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). Chevron deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at Chevron's "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., MCI v. AT&T, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" always overlaps with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application delayed under § 154(b)(1)(B) during the

period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and no more, it could easily have been written that way. It is true that the legislative context -- as

distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, et al., :
: Plaintiff, :
: v. : Civil Action No. 07-1492 (JR)
: JON W. DUDAS, Under Secretary of :
Commerce for Intellectual :
Property and Director of U.S. :
Patent and Trademark Office, :
: Defendant. :

ORDER

For the reasons stated in the accompanying memorandum opinion, plaintiffs' motion for summary judgment [12] is **GRANTED** and defendant's motion for summary judgment [16] is **DENIED**. The case is remanded to the agency for further proceedings that are consistent with this opinion.

JAMES ROBERTSON
United States District Judge